Department of Veterans Affairs **VHA DIRECTIVE 2001-028**
Veterans Health Administration
Washington, DC 20420 **April 27, 2001**

RESEARCH INVOLVING CHILDREN

1. PURPOSE: This Veterans Health Administration (VHA) Directive implements the policy on the exclusion of children as research subjects in Department of Veterans Affairs (VA)-approved research, unless a waiver has been obtained from the Chief Research and Development Officer (CRADO).

2. BACKGROUND

a. VA is authorized to care for veterans and to conduct research that supports the mission of VHA and enhances the quality of health care delivery to veterans.

b. The majority of VA facilities are not accustomed to caring for children, and the majority of the staff and Institutional Review Board (IRB) members may not have sufficient expertise in pediatrics and pediatric research to ensure the safety of children participating in research.

c. A child is defined as any person who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted.

d. VA-approved research is defined as any research that has been approved by the VA Research and Development (R&D) Committee, conducted by VA investigators while on duty, or conducted at VA facilities or approved off-site locations.

3. POLICY: It is VHA policy that children can not be included in VA-approved research conducted by VA investigators while on duty, or conducted at VA facilities or approved off-site locations, unless a waiver has been granted by the CRADO. ***NOTE:*** *Congressionally-mandated research programs that involve children are exempt from this policy*.

4. ACTION

a. Each VA facility conducting research must submit to the Office of Research and Development (ORD) a list of all active research projects that involve children, no later than 30 days after the issuance of this directive. This list is to include the:

(1) Name of the protocol.

(2) Name of the Principal Investigator.

(3) Level of risk.

(4) Sponsor of the research.

(5) Start date and anticipated completion date of the research.

THIS VHA DIRECTIVE EXPIRES APRIL 30, 2006

b. VA facilities currently conducting research that involve children must apply for and receive, for each protocol involving children, a waiver from the CRADO before October 1, 2001. If a waiver has not been received for a protocol involving children by that date, the protocol is terminated, and the principal investigator must arrange for the safe transition of the subjects out of the study, with appropriate continuation of medical care by the subjects' physicians.

c. No new research involving children can be initiated after April 20, 2001, unless a waiver has been granted by the CRADO.

d. Prior to requesting a waiver, the following criteria must be met:

(1) The study represents no greater than minimal risk.

(2) The study meets all requirements in Title 45 Code of Federal Regulations (CFR) Part 46, Subpart D, "Additional DHHS Protections for Children Involved as Subjects in Research."

(3) The IRB reviewing the study must have appropriate membership to represent childrens' interests and pediatric expertise.

(4) The IRB reviewing the study must have specific policies and procedures regarding children in research.

(5) The medical center Director must certify that the facility is able to respond to pediatric emergencies.

(6) If a contractor and/or a non-VA employee conducts the research, the facility must make certain that the individual, or entity performing the research, has procured appropriate liability insurance.

e. To request a waiver, the following information must be submitted to ORD for each protocol:

(1) A cover letter signed by the medical center Director that contains the following information:

(a) Certification by the medical center Director that the facility is able to respond to pediatric emergencies.

(b) Any additional safeguards that have been incorporated into the clinical site where children will be studied.

(c) Information on the study's funding source.

(d) Information on whether the research will be conducted by a contractor and/or by non-VA employees and, if so, the liability coverage for the study.

(e) Certification that the IRB has determined the study to be of no greater than minimal risk and has approved the study.

(f) A statement that the required elements have been met.

(g) A description of the relevance of both the study and the inclusion of children in the study to veterans' health.

(2) A copy of the study protocol, the informed consent form, and the assent document.

(3) Minutes of the IRB and R&D Committee meetings approving the study. The IRB minutes should reflect the discussion regarding level of risk, the consent and assent forms, the investigators' qualifications to conduct research involving children, and any additional safeguards incorporated into the protocol.

5. REFERENCES: Title 45 CFR Part 46, Subpart D.

6. FOLLOW-UP RESPONSIBILITY: The Office of the Chief Research and Development Officer (12) is responsible for the contents of this directive.

7. RESCISSIONS: None. This Directive expires April 30, 2006.

S/ Dennis H. Smith for
Thomas L. Garthwaite, M.D.
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 5/1/2001
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 5/1/2001